



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

May 25, 2005

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Steven G. Wigrizer, Esq.  
Wapner, Newman, Wigrizer, & Brecher  
115 South 21<sup>st</sup> Street  
Philadelphia, PA 19103-4483

Re: Docket No. 2004P-0220/CP1

Dear Mr. Wigrizer:

This letter responds to your citizen petition received on May 7, 2004, and amended on May 17, 2004, requesting that the Food and Drug Administration (FDA) determine whether Zithromax (azithromycin) 250-milligram (mg) oral capsules were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Zithromax (azithromycin) 250-mg oral capsules were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Zithromax (azithromycin) 250-mg oral capsules in the Discontinued Drug Product List of the *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 443-5540.

Sincerely,

Elizabeth Sadove  
Division of Regulatory Policy I  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure

2004 P-0220

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to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:**

Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS-666), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1697, or e-mail: [dcarrington@cfsan.fda.gov](mailto:dcarrington@cfsan.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On December 1, 2004, CFSAN released a document entitled "FY 2005 CFSAN Program Priorities." The document, a copy of which is available on CFSAN's Web site ([www.cfsan.fda.gov](http://www.cfsan.fda.gov)) or from the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section, constitutes the Center's priority workplan for FY 2005 (i.e., October 1, 2004, through September 30, 2005). The FY 2005 workplan is based on input we received from our stakeholders (see 69 FR 35380, June 24, 2004), as well as input generated internally. The primary focus is: "Where do we do the most good for consumers?"

The FY 2005 workplan contained three lists of activities, as follows: The "A-list," the "B-list," and a "Priority Ongoing Activities" list. Our goal is to complete fully at least 90 percent of the "A-list" activities by the end of the fiscal year, September 30, 2005. Activities on the "B-list" are those we plan to make progress on, but may not complete before the end of the fiscal year. Items in the "Priority Ongoing Activities" list illustrate some of the many priority activities the Center performs on a regular basis in addition to those identified on our "A" and "B" lists.

CFSAN intends to issue a progress report on what program priority activities already have been completed to date in the summer of FY 2005, as well as any adjustments in the workplan (i.e., additions or deletions) for the balance of the fiscal year.

**II. 2006 CFSAN Program Priorities**

FDA is requesting comments on what program priorities CFSAN should consider establishing for FY 2006. The input will be used to develop CFSAN's FY 2006 workplan. The workplan will set forth the Center's program priorities for the period of October 1, 2005, through September 30, 2006. FDA intends to make the FY 2006 workplan available in the fall of 2005.

The format of the FY 2006 workplan will be identical to the FY 2005 plan, and it will be formatted into the following five sections:

- (1) Ensuring Food Defense and Security,
  - (2) Improving Nutrition and Dietary Supplement Safety,
  - (3) Ensuring Food/Color Additives and Cosmetic Safety,
  - (4) Ensuring Food Safety: Crosscutting Areas, and
  - (5) Priority Ongoing Activities.
- FDA expects there will be considerable continuity and followthrough between the 2005 and 2006 workplans. For example, initiatives aimed at increasing the security of our country's food supply will continue to be a high priority in FY 2006. FDA requests comments on other broad program areas that should continue to be a priority, as well as new program areas or activities that should be added as a high priority, for FY 2006.

**III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-10033 Filed 5-19-05; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket 2004P-0220]

**Determination That ZITHROMAX (Azithromycin) 250-Milligram Oral Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that ZITHROMAX (azithromycin) 250-milligram (mg) oral capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug

applications (ANDAs) for azithromycin 250-mg oral capsules.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Sadove, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ZITHROMAX (azithromycin) 250-mg oral capsules are the subject of NDA 50-670 held by Pfizer, Inc. (Pfizer). FDA approved NDA 50-670 on November 1, 1991. In February 1994, Pfizer submitted NDA 50-711 for ZITHROMAX (azithromycin) 250-mg tablets. Pfizer explained that the new dosage form was intended to replace the capsule formulation. Pfizer decided to change the dosage form from capsules to tablets because tablets do not have a

food effect. In its February 15, 1994, letter accompanying NDA 50-711, Pfizer explained that the tablets are bioequivalent to the capsule formulation and " \* \* \* unlike the capsule, can be taken without regard to meals." After NDA 50-711 was approved, Pfizer decided not to market the capsule formulation and ZITHROMAX (azithromycin) 250-mg oral capsules were moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

In a citizen petition submitted under 21 CFR 10.30 dated May 4, 2004 (Docket No. 2004P-0220), as amended by a letter dated May 17, 2004, Wapner, Newman, Wigrizer & Brecher requested that FDA determine whether ZITHROMAX (azithromycin) 250-mg oral capsules were withdrawn from sale for reasons of safety or effectiveness. The agency has determined that ZITHROMAX (azithromycin) 250-mg oral capsules were not withdrawn from sale for reasons of safety or effectiveness. The petitioners identified no data or other information suggesting that ZITHROMAX (azithromycin) 250-mg oral capsules were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this document, ZITHROMAX (azithromycin) 250-mg oral capsules, approved under NDA 50-670, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZITHROMAX (azithromycin) 250-mg oral capsules in the "Discontinued Drug Product List" section of the Orange Book. As a result, ANDAs that refer to ZITHROMAX (azithromycin) 250-mg oral capsules may be approved by the agency.

Dated: May 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-10032 Filed 5-19-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the following committee will convene its fiftieth meeting:

*Name:* National Advisory Committee on Rural Health and Human Services.

*Dates and Times:* June 12, 2005, 1:30 p.m.-5:15 p.m., June 13, 2005, 8:45 a.m.-5 p.m., June 14, 2005, 9 a.m.-10:45 a.m.

*Place:* Carnegie Hotel, 1216 W State of Franklin Road, Johnson City, TN 37604, Phone: 423-979-6400, Fax: 423-979-6424.

*Status:* The meeting will be open to the public.

*Purpose:* The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

*Agenda:* Sunday afternoon, June 12, at 1:30 p.m., the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. There will be a brief discussion of Committee business and updates by Federal staff. The first session will open with an overview of East Tennessee by Dr. Paul Stanton, President of East Tennessee State University. The remainder of the day's meeting will be devoted to panel discussions on the three topics for the 2006 workplan: Pharmacy Access, Health Information Technology (HIT), and Elderly Caregiver Support. The Sunday meeting will close at 5:15 p.m.

Monday morning, June 13, at 8:45 a.m., the Committee will break into Subcommittees and conduct site visits to local health and human services facilities. Transportation to these sites will not be provided to the general public. The Pharmacy Access Subcommittee will visit Wilson Pharmacy in Johnson City; the HIT Subcommittee will visit Central Appalachian Health Information Partnership in Mountain City; and the Elderly Caregiver Support Subcommittee will visit the Mountain Empire Older Citizens Area Agency on Aging in Big Stone Gap. The Subcommittees will reconvene at 1:45 p.m. at the Carnegie Hotel to continue discussions on the workplan. The Committee of the whole will reconvene at 4:30 p.m. for a brief discussion of the workplan. The Monday meeting will close at 5 p.m.

The final session will be convened Tuesday morning, June 14, at 9 a.m. The Committee will review the discussion of the 2006 Workplan and have updates on the Subcommittees site visits. The meeting will conclude with a discussion of the September meeting. The meeting will be adjourned at 10:45 a.m.

*For Further Information Contact:* Anyone requiring information regarding the

Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), telephone (301) 443-0835. The Committee meeting agenda will be posted on ORHP's Web site <http://www.ruralhealth.hrsa.gov>.

Dated: May 13, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-10098 Filed 5-19-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Opportunity for a Cooperative Research and Development Agreement (CRADA) for Research and Development of Vigabatrin as a Potential Pharmacotherapy for the Treatment of Cocaine and Methamphetamine Dependence

**AGENCY:** National Institutes of Health, PHS, DHHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute on Drug Abuse, a component of the National Institutes of Health, Department of Health and Human Services (DHHS) seeks an agreement with a pharmaceutical or biotechnology company to test the hypotheses that vigabatrin may be a safe and effective medication for the treatment of cocaine and methamphetamine dependence.

A body of literature relevant to preclinical studies of vigabatrin as a potential treatment agent for various types of substance dependence (including cocaine and methamphetamine) and a more limited body of literature concerning clinical results exists. As there are currently no medications approved by the U. S. Food and Drug Administration (FDA) for the treatment of cocaine and/or methamphetamine dependence, and cocaine and methamphetamine dependence have substantial negative public health impacts, the National Institute on Drug Abuse is interested in evaluating the safety and efficacy of vigabatrin for the treatment of cocaine and methamphetamine dependence.